COGR
an organization of research universities

COUNCIL ON GOVERNMENTAL RELATIONS
1200 New York Avenue, N.W., Suite 320, Washington, D.C. 20005
(202) 289-6655/(202) 289-6698 (FAX)

June 4, 2002

Mr. Phillip L. Chao
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, Maryland 20852

Electronic: http://www.fda.gov/dockets/ecomments

SUBJECT: Advanced Notice of Proposed Rulemaking (ANPRM): Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews

Dear Mr. Chao:

The Council on Governmental Relations (COGR) is an association of over 145 research-intensive universities in the United States. COGR works with federal agencies and research sponsors to develop a common understanding of the impact that policies, regulations and practices may have on the research conducted by the membership.

We appreciate the Food and Drug Administration (FDA) providing the opportunity to comment, in advance, on the possible expansion of the investigator and sponsor disclosure requirements and responsibilities of the Institutional Review Boards (IRB). University-based IRBs conduct thousands of clinical research reviews each year and work to ensure a thorough and accurate review. The system relies on full and honest disclosure by investigators and each university is committed to support its IRB and investigators in meeting their obligations. As a consequence, we are very interested in any proposed changes that affect the review process.

As you know, the Office of the Inspector General (OIG) in the Department of Health and Human Services produced a series of reports in 1998 that examined the operations of IRBs. In the report entitled *Institutional Review Boards: A Time for Reform*, the OIG described anecdotal evidence of a "few situations" of "IRB shopping." This brief description by the OIG does not provide an adequate factual basis for the determination that IRBs lack sufficient information to exercise good judgment, and, as a consequence, should be subjected to new regulations. The first question posed in the ANPRM seeks information on the scope

and effect of the phenomenon but the responses are likely to only provide additional anecdotes that would compound the problem. Until there is sufficient evidence of a pervasive problem, it would be premature for the FDA to amend its regulations. We suggest that the FDA sponsor or commission a study, or a series of studies, that examine the questions posed in the ANPRM in the context of the role and responsibilities of the IRB. The current regulations protect the independence of the IRBs by prohibiting institutions from conducting research that has not received IRB approval. The IRB is required to seek appropriate expertise and assistance in conducting its review. The knowledge of the results of another, prior review may be helpful but that disclosure cannot substitute for a thorough and comprehensive local review. The FDA should consider the broader foundation of responsibilities and requirements before proceeding with any change in the regulations.

In the same 1998 report cited above, the OIG makes a number of recommendations including the support of more routine communications to "provide IRBs with regular feedback on developments concerning multi-site trials" (Recommendation 2.b. and 2.c.). We believe that the need for effective communications is a more compelling issue than IRB shopping. If the FDA is considering additional changes based on the OIG's 1998 recommendations, it may want to include questions in the proposed studies that examine those concerns because any proposed regulatory change should be supported by good documentation. Executive Order 12866 directs federal agencies to promulgate only those regulations that address a compelling public need, proceeding after clearly identifying the problem and assessing its significance.

The OIG highlighted the problem of overburdening IRBs with procedural requirements and "perfunctory review responsibilities." We share the OIG's belief that the IRB needs to focus on its key responsibility – to concentrate their attention on those research practices posing the greatest risks to human research participants.

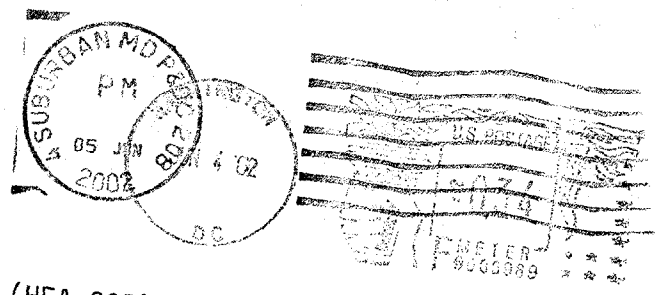
Thank you for the opportunity to comment the ANPRM.

Sincerely,

K. Phillips.

Katharina Phillips

...AL RELATIONS
...New York Avenue, N.W. • Suite 320
Washington, D.C. 20005



Mr. Phillip L. Chao
Dockets Management Brnach (HFA-305)
Food and Drug Administration
5630 Risher Lane
Room 1061
Rockville, Maryland 20852